(1)

Contains NO CBI

RHÔNE-POULENC

RHÔNE-POULENC INC.
CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE: (609) 395-8300

(A)

OCT [illegible] AM 9:31

October 23, 1992

8EHQ-92-12609

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 416 555 423

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0350

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Chemical Identity: Aluminum sulfate hydrate

CAS Registry No: 10043-01-3

CAS Registry Name: Sulfuric acid, aluminum salt

3/8/95

(2)

The title of the enclosed report is:

Toxicology Laboratory Report T-4874

The following is a summary of the adverse effects observed in this report

The test material was found to be a severe eye irritant. Conjunctivitis and corneal opacity were seen throughout the observation period with very little evidence of reversibility (pH = 3.5 of 1% solution).

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance.

In total, RPI is submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

CEMjr/mm
Enclosures

BEGIN REPORT

T-4874

REVIEWED FOR THE SECTION 8(e) COMPLIANCE AUDIT PROGRAM, ON 3-2-92 BY RDF/JC2. CAD ID NO. B-CB-RDF-10

CONFIDENTIAL

TOXICOLOGY REQUEST FORM

T-No. 4874

Project No. 70-0110

Compound Aluminum Sulfate Hydrate (Alum) Date 3/22/74

Identification (lot, batch, etc.) CBE-1636-CBE-4

Use (insect., herbicide, etc.) Paper manufacturing ingredient

STRUCTURE

Purity (%) 57.0%
by (IR, m.p., etc)
Known Impurities

Complete for formulations:

Per cent technical
solvent
per cent

- -

Check and Complete:

- ☐ Acute oral toxicity - species
- ☐ Acute dermal toxicity - rabbits
- ☒ Primary skin irritation (Industrials) - rabbits DOT
- ☒ Acute eye irritation - rabbits
- ☐ Other (specify)

- -

Report Distribution O. Overmann (W), A. Lupenski (W), J. VanLaer (W), A Green (Bastrop Plant, LA.)

Remarks

265-19-220-10-69-5M

Requested By J. A. VanLaer

CONFIDENTIAL

STAUFFER CHEMICAL COMPANY
WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

cc: J. F. Heil
R. L. Joiner
C. J. O'Connor, Wepto
O. Overman "
A. Lupenski, "
J. vanLaer, "
A. Green, Bastop Plant, LA.

10/30/74

TOXICOLOGY LABORATORY REPORT -- T- 4874

ALUMINUM SULFATE HYDRATE

I. OBJECTIVE

To evaluate the toxicological aspects of this material.

II. MATERIALS

ALUMINUM SULFATE HYDRATE, 088-1638-088-4, a white powder, was received from Industrial Chemical Division on 3/22/74.

III. SUMMARY

A. Skin irritation classification: noncorrosive (4-hr. exposure)

B. Eye irritation classification: severe irritant

Submitted by Pedro Jimenez
P. Jimenez

Approved by R L Joiner
R. L. Joiner

RLJ:ea

A. PRIMARY SKIN IRRITATION, DOT PROTOCOL **CONFIDENTIAL**

TEST MATERIAL: ALUMINUM SULFATE HYDRATE T-4874

Skin irritation classification: noncorrosive

Primary skin irritation was determined according to the proposed FDA revision of the test for primary skin irritants published in the Code of Federal Regulations (Part 191, Chapter 1, Title 21) for evaluating hazardous substances.

The proposed test differs from the procedure described in the Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21, in that irritation is determined after a 4-hour exposure period rather than after the previously required 24-hour exposure period. In the proposed test, readings are made 4- 24- and 48-hours after treatment. Animals are to be retained for observation 96 hours after initial application. Any delayed necrosis will be reported, but the data will not be used in determination of irritation indices. A corrosive substance is defined as a material that causes tissue destruction within 48 hours after application on any of the twelve intact sites.

Rabbit No.	Skin	Erythema-eschar Observation 4 hr.	24 hr.	48 hr.	Edema Observation 4 hr.	24 hr.	48 hr.	Sum Total	Score*
1	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
2	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
3	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
4	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
5	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
6	Intact	0 0	0 0	0 0	0 0	0 0	0 0	0	0
Primary Irritant Score ----------									0

*Score = Sum of individual values for each rabbit divided by six.

Observation: Rabbits appeared normal at observation times.

B. EYE IRRITATION

CONFIDENTIAL

TEST MATERIAL ALUMINUM SULFATE HYDRATE T- 4874

Eye Irritation Classification: severe irritant

The procedure employed is in accordance with the test for eye irritants outlined in the code of Federal Regulations (Part 191.12, Chap. 1, Title 21) for evaluating hazardous substances.

Six New Zealand rabbits in the 1.6-2.1 kg weight range were used as the test animals. The test material was placed in one eye of each animal by gently pulling the lower lid away from the eyeball to form a cup into which the test material is dropped. The lids were gently held together for three seconds and the animal released. The other eye, remaining untreated, served as the control. The eyes were observed at 24- 48- and 72-hours following treatment and scored for irritation properties.

Quantity instilled into each test site: 10 mg

Corneal Damage: The first two days after dosing all rabbits had moderate or severe corneal opacity over the entire corneal area, and on the third day these symptoms were either slight or moderate except for one rabbit which developed chemosis to the extent the cornea could not be observed. By the 7th day 4 rabbits had slight corneal opacity while two had moderate opacity.

Iritis: none

Conjunctivae,

a) erythema: One rabbit displayed severe erythema at all observation time Three rabbits had severe erythema the first three days and slight erythem on the 7th day. Two rabbits had moderate symptoms the first two days, slight symptoms the 3rd, and on the 7th day one had no erythema while the last returned to moderate symptoms.

b) chemosis: Two rabbits had severe chemosis for all four observation times, and of these 2, chemosis was severe enough in one to render the eye unobservable. The remaining four rabbits had slight to moderate chemosis for 3 days and slight chemosis on the 7th day.

c) discharge: Four rabbits had slight to moderate discharge over each of the four observation times. One had severe discharge for three days and slight discharge on the 7th day. The last rabbit had severe discharg all 4 days.

Signs of Remission: With respect to corneal opacity all rabbits with severe symptoms the first day had moderate symptoms on the 7th, and all rabbits with moderate symptoms the first day had slight symptoms on the 7 With respect to the conjunctivae, one rabbit had severe symptoms throughout the observation period. Another rabbit had moderate to severe symptoms throughout. The remaining four rabbits had moderate or severe symptoms the first day and slight symptoms by the 7th.

Additional Comments: none

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

From § 191.11, paragraph (c), the following TABLE:

Skin Reaction	Value
Erythema and eschar formation:	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Edema formation:	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

SKIN IRRITATION INDEX (DOT PROCEDURE)

T-4874

CONFIDENTIAL

10-174

COMPOUND ALUMINUM SULFATE HYDRATE

11.00

Rabbit No.	Skin	Erythema-eschar Observation 4 hr.	24 hr.	48 hr.	Edema Observation 4 hr	24 hr.	48 hr.	Sum Total	Sec
1	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		
2	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		
3	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		
4	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		
5	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		
6	Intact	0	0	0	0	0	0		
		0	0	0	0	0	0		

Primary Irritant Score ----------

*Score = sum of individual values for each rabbit divided by six.

Observations:

kin Irritant Score and
rritant Classification

Test site	Evaluation of skin reaction	Ratio regarding six rabbits Observation time 4 hours	24 hours	48 hrs.
Intact	Corrosive			

Eye Irritation Study — Beginning Date: 10-7-74 — 1-4874

OBSERVATION INTERVALS

Animal #			1 hr	1 day	2 days	3 days	7 days	14 days
wt:	Cornea	Opacity (0-4)		2	2	2	1	
sex: ♂ F		Area (0-4)		4	4	4	4	
2	Iris (0-2)			0	0	0	0	
	Conjunctiva:	Redness (0-3)		3	3	3	1	
		Chemosis (0-4)		2	2	2	1	
		Discharge (0-3)		2	2	2	2	
	Fluorescein Staining		P C	P C	P C	P C	P C	P C
wt:	Cornea	Opacity (0-4)		2	2	1	1	
sex: ♂ F		Area (0-4)		4	4	4	4	
13	Iris (0-2)			0	0	0	0	
	Conjunctiva:	Redness (0-3)		3	3	3	1	
		Chemosis (0-4)		2	2	1	1	
		Discharge (0-3)		3	3	3	1	
	Fluorescein Staining		P C	P C	P C	P C	P C	P C
wt:	Cornea	Opacity (0-4)		3	3	1	1	
sex: ♂ F		Area (0-4)		4	4	4	4	
4	Iris (0-2)			0	0	0	0	
	Conjunctiva:	Redness (0-3)		3	3	3	1	
		Chemosis (0-4)		2	2	2	1	
		Discharge (0-3)		2	3	3	1	
	Fluorescein Staining		P C	P C	P C	P C	P C	P C
wt:	Cornea	Opacity (0-4)		3	3	2	3	
sex: M ♂		Area (0-4)		2	4	4	4	
28	Iris (0-2)			0	0	0	0	
	Conjunctiva:	Redness (0-3)		3	3	3	3	
		Chemosis (0-4)		3	3	3	3	
		Discharge (0-3)		3	3	3	3	
	Fluorescein Staining		P C	P C	P C	P C	P C	P C
wt:	Cornea	Opacity (0-4)		2	2	1	1	
sex: M ♂		Area (0-4)		4	4	4	4	
29	Iris (0-2)			0	0	0	0	
	Conjunctiva:	Redness (0-3)		3	2	1	0	
		Chemosis (0-4)		3	2	1	1	
		Discharge (0-3)		2	2	2	1	
	Fluorescein Staining		P C	P C	P C	P C	P C	P C
wt:	Cornea	Opacity (0-4)		3	—	—	2	
sex: M ♂		Area (0-4)		4	—	—	4	
30	Iris (0-2)			0	—	—	—	
	Conjunctiva:	Redness (0-3)		2	2	1	2	
		Chemosis (0-4)		3	3	4	3	
		Discharge (0-3)		2	2	1	2	
	Fluorescein Staining							

LL = lack luster; Pa = pannus; Pl = phlyctenule; Py = phlyctena; N = necrosis; C = circumcorneal injection
H = histopathology; P = punctate; C = confluent; NI = not irrigated ; I = irrigated

Form Revised 3/73

CONFIDENTIAL

Triage of 8(e) Submissions

Date sent to triage: 2/5/96

Submission number: 12609A

NON-CAP CAP

TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1,2 **pages** 1,2, tab

Notes: 2sided.

Contractor reviewer : LPS **Date:** 5/11/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 -12609 SEQ A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc Inc.

SUB. DATE: 10/23/92 OTS DATE: 10/23/92 CSRAD DATE: 03/08/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
0639 REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKER HISTORY
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:

CAS#
10043-01-3

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL. TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	0248	PROD/USE/PROC	01 02 04
0209	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
0212	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA: CAS SR

NON-CBI INVENTORY
YES
NO
UNDETERMINED

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
RBT

TOXICOLOGICAL CONCERN:
LOW Dermal Irritation
MED Ocular Irritation
HIGH

USE: paper manuf. ingredient

PRODUCTION:

COMMENTS

#12609A
M

Ocular irritation is of medium concern based on severe irritation (moderate to severe corneal opacity, severe conjunctival erythema, chemosis and discharge), with symptoms lessening somewhat over the 7 day observation period.

L

Dermal irritation is of low concern based on no irritation in 6/6 rabbits.